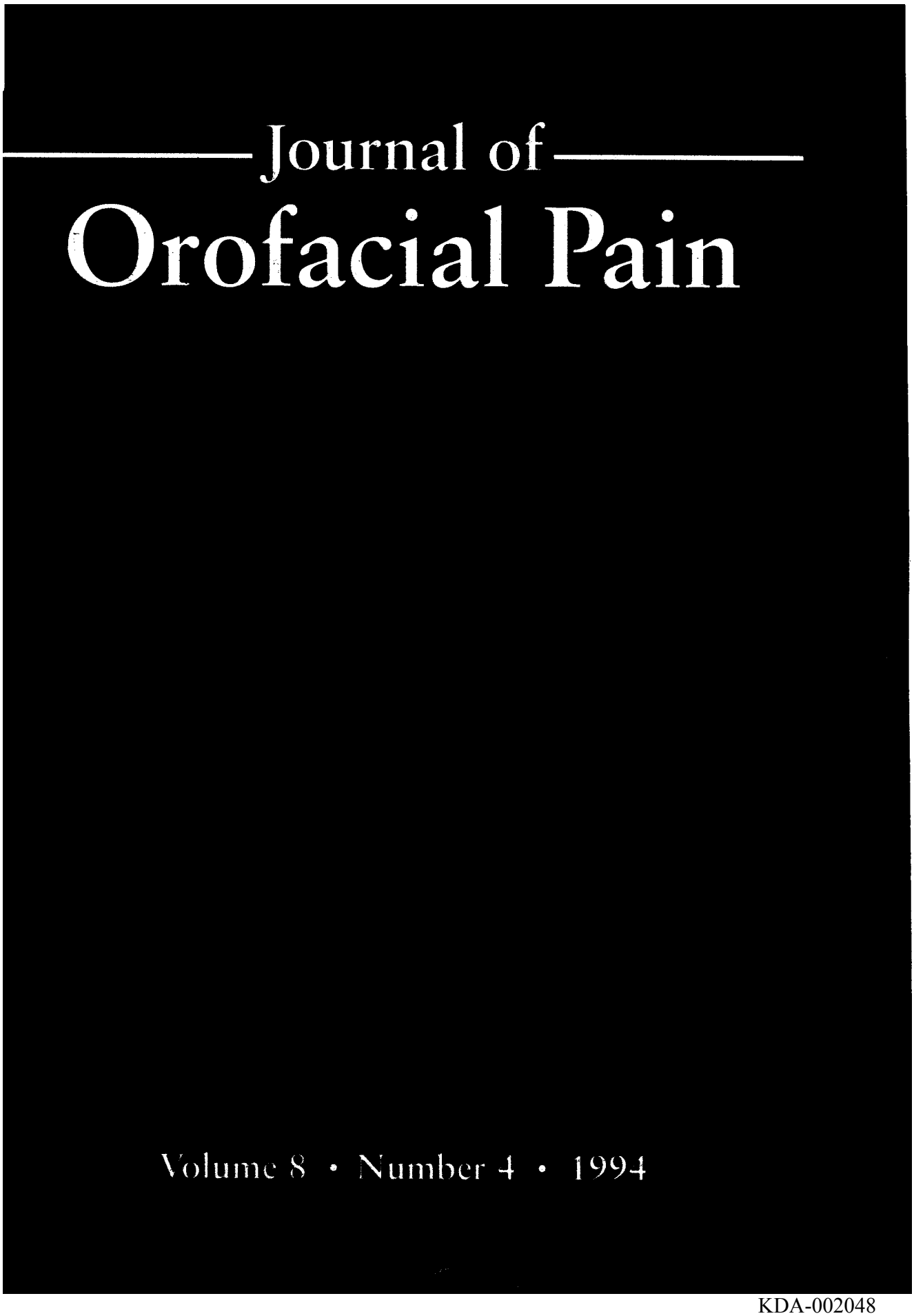


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EXHIBIT 68

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EXHIBIT 68

# Comparison of Pain and Quality of Life in Bruxers and Patients With Myofascial Pain of the Masticatory Muscles

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*Although it has been suggested that bruxism is a cause or a risk factor in myofascial pain of the masticatory muscles, the prevalence of pain in bruxers and its characteristics have not been assessed or compared to those of myofascial pain patients in general. In this study, self-reports of pain and quality of life were recorded on 100-mm visual analogue and five-point category scales from two research populations: (1) 19 nocturnal bruxers who participated in a polysomnographic study and (2) 61 patients with myofascial pain of the masticatory muscles with no evidence of bruxism who participated in a controlled clinical trial on the efficacy of oral splints. The data show that pain was more intense in those bruxers who reported pain than among the myofascial pain patients, even though pain was not the chief complaint of bruxers. Both conditions reduced the patient's quality of life, although pain patients (either bruxism or myofascial pain) appeared to be much more affected than bruxers who were pain-free. The fact that pain from bruxism was worst in the morning suggests that it is possibly a form of postexercise muscle soreness. Myofascial pain, which was worst late in the day, is likely to have a different etiology.*
J OROFACIAL PAIN 1994;8:350–356.

The temporomandibular disorders (TMD) include myofascial pain, disc displacements within the temporomandibular joint and the arthritides.[1] Previous studies indicate that 43% to 50% of myofascial pain patients[2,3] and 26.6% to 66% of TMD patients[4–6] reported that they brux their teeth. This led to speculation that bruxism may constitute a risk or an etiologic factor for these conditions.[7–11] It has also been proposed that bruxism should be considered a condition separate from myofascial pain.[12] In fact, only some bruxers have facial pain.[4,7,8,10,11,13,14] To the authors' knowledge, the prevalence of pain in bruxers and its characteristics, particularly intensity and diurnal pattern, have not been assessed or compared to those of myofascial pain patients.

This study compares the pain reports of bruxers and myofascial pain patients and describes the effects of these conditions on their daily activities. Measurements of pain were made on visual analog scales (VAS), and quality of life was assessed using category scales (CAT). A short preliminary report has been published.[15]

## Materials and Methods

### Population

The sample populations were 19 subjects who participated in a polysomnographic study of nocturnal bruxism and 61 subjects with

myofascial pain of the masticatory muscles enrolled in a controlled clinical trial to evaluate the efficacy of oral splints.[16] They were French-speaking whites recruited through announcements published in local newspapers or referred by dentists to the research clinic. All subjects gave informed consent to procedures approved by the Institutional Human Subjects Ethics Committees (Hôpital du Sacré Coeur and Université de Montréal).

The bruxism group had 10 males and 9 females, healthy and drug-free, aged 22 to 36 years (mean = 27.7, ± 4.1 [SD]). All subjects had a chief complaint of nocturnal tooth grinding. They had become aware of their condition or were informed by their sleep partner that they made frequent grinding noises. They all participated in a descriptive study of nocturnal bruxism and its relationship to sleep states.[17] Bruxism was confirmed by polysomnographic recordings during two consecutive nights in a sleep laboratory, using the criteria of the International Classification of Sleep Disorders.[18]

In the myofascial pain group, there were 10 males and 51 females, aged 16 to 45 years (mean = 30.7 ± 7.5). The selection criteria for myofascial pain have already been described.[16] In summary, the patients had a chief complaint of frequent facial pain (at least four times per week) of at least 12 weeks duration and a positive report of tenderness to palpation of at least three sites in the masticatory muscles. Patients with clinical evidence or report of bruxism (severe tooth wear, self-awareness of bruxism, or sleep partner's report of nocturnal grinding noises) were excluded.

### Experimental Procedures

During the screening visit, all subjects rated their current pain intensity on a VAS. Subjects who had pain were asked when it was usually worst and least (morning, afternoon, or evening). Using a five-point category scale (CAT: 0 = "pas du tout" [not at all], 1 = "un peu" [a little], 2 = "modérément" [moderately], 3 = "beaucoup" [a lot], 4 = "extrêmement" [extremely]), the subjects indicated to what extent their orofacial condition disturbed their sleep, social activities, and appetite; decreased their efficiency at work; made them feel tense and depressed; and made speech and mastication difficult. Any score from 1 to 4 was rated as a positive response. These quality of life variables were based on self-reports of symptoms associated with myofascial/TMD pain that have been published.[2,9,19–22]

### Statistical Analysis

Between-group comparisons were made using analysis of variance (ANOVA) for data from the VAS. Chi-square tests were used for CAT data.

## Results

Since the subjects from the two studies were recruited for different purposes and because of the differences in the sex distribution between groups, the data presented here must be interpreted with caution.

### VAS Data

Although no bruxers complained about pain when they were first interviewed, the group had a mean pain intensity (± SE) of 18.3 ± 7.0 mm. This group mean is lower than that of myofascial pain patients (35.2 ± 2.7 mm). However, pooling the data from all bruxers hides the fact that there were 13 (6 females, 7 males) pain-free bruxers (VAS = 0 mm) while the 6 others (3 females, 3 males) reported high levels of pain (58.0 ± 10.0 mm), and this is significantly higher than that of myofascial pain patients ($t[65] = -2.46$, $P = .01$) (Table 1). All bruxers with pain reported that they still had pain when they were seen at the sleep laboratory approximately 1 month later.

### Time of Pain Occurrence

Five of the six bruxers with pain (83.3%) reported that their pain was worst in the morning and least in the evening; only one had his worst pain in the evening. Opposite results were found for the myofascial pain group; the pain of the majority (50.8%) was worst in the evening and least in the morning. Only 19.7% had their highest pain in the morning (Fig 1).

### Quality of Life

When data from all 19 bruxers were compared to those of the myofascial pain group, fewer bruxers than myofascial pain subjects reported disturbances of quality of life (Table 2). However, the prevalence of reduced quality of life was comparable between bruxers with pain and myofascial pain patients. Since no significant statistical difference was found between these two groups, their data were pooled and contrasted to those of the pain-free bruxers. Although patients from both of these pain groups appeared to be more affected than the pain-free bruxers for all variables, significant overall between-group differences were found for only

**Table 1** Mean Pain Intensity (± SE) in Bruxers and Myofascial Pain Patients

| All bruxers (n = 19) | Myofascial pain (n = 61) | Bruxers with pain (n = 6†) |
|---|---|---|
| 18.3 ± 7.0 mm | 35.2 ± 2.7 mm * | 58.0 ± 10.0 mm |

†A subgroup from the 19 bruxers.
*($t[65] = -2.46$; $P = .01$).

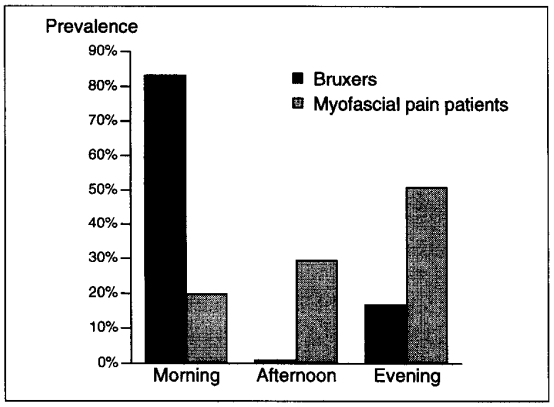


**Fig 1** Most bruxers with pain experienced their highest pain in the morning. Half the group of myofascial pain patients had their worst pain in the evening.

**Table 2** Reports of Quality-of-Life Disturbances (%)

| | All bruxers (n = 19) | Myofascial pain (n = 61) | Bruxers with pain (n = 6†) | | Bruxers without pain (n = 13†) |
|---|---|---|---|---|---|
| Disturbed sleep | 36.8 | 59.0 | 66.7 | | 30.8 |
| Disturbed social activities | 10.5 | 55.7 | 33.3 | | 0.0 |
| Disturbed appetite | 5.3 | 50.8 | 16.7 | | 0.0 |
| Decreased efficiency at work | 15.8 | 63.9 | 33.3 | | 7.7 |
| Feeling tense | 42.1 | 83.6 | 83.3 | * | 23.1 |
| Feeling depressed | 10.5 | 45.9 | 33.3 | ** | 0.0 |
| Difficulty with speech | 15.8 | 49.2 | 33.3 | | 7.7 |
| Difficulty with mastication | 36.8 | 80.3 | 83.3 | *** | 15.4 |

†Subgroups from the 19 bruxers.
*$\chi^2$ (2) = 9.5, $P = .008$.
**$\chi^2$ (2) = 14.8, $P = .0006$.
***$\chi^2$ (2) = 14.3, $P = .0008$.

three variables: "decreased efficiency at work" ($\chi^2[2] = 9.5$, $P = .008$); "feeling tense" ($\chi^2[2] = 14.8$, $P = .0006$); and "difficulty during mastication" ($\chi^2[2] = 14.3$, $P = .0008$). For these items, the prevalence in the pain-free bruxers was significantly lower than in the other two groups pooled together: "decreased efficiency at work" ($\chi^2[1] = 4.6$, $P = .03$); "feeling tense" ($\chi^2[1] = 10.4$, $P = .001$); "difficulty during mastication" ($\chi^2[1] = 11.3$, $P = .0008$); Table 2.

## Discussion

Although pain was not the presenting complaint of sleep bruxers, the data show that it was significantly more intense in those bruxers who reported pain than among myofascial pain patients. Pooling data from all bruxers hides the fact that some report high levels of pain while more than half are pain free. It is interesting to note that the mean pain reported by the bruxers with pain in our study (58 mm) exceeds the level of myofascial/TMD pain previously published (20 to 48.6 mm on VAS),[3,23,24] even though pain was not their chief complaint. Another difference is that the majority of bruxers with pain reported that their pain was worst in the morning, and most of the myofascial pain patients had their worst pain in the evening. Both conditions reduce the patients' quality of life, although pain patients appear to be more affected than bruxers who are pain free.

The finding that some bruxers experience pain confirms many earlier studies,[1,7,8,10,11,13,14,25] and the prevalence of pain in this bruxer group is within the range reported by others. For instance, Goulet et al[11] found that about one fifth of subjects who

were aware of parafunctional habits experienced jaw pain. Thirty percent of the bruxers who participated in the survey carried out by Houston et al[26] had pain in the face and jaws. Higher prevalences have been reported in some studies (44% to 59%),[10,13] but these authors associated any pain in the head, neck, or teeth with bruxism. On the other hand, other workers found no association or even a negative association between the signs and symptoms of bruxism and of TMD.[27,28] In these two studies, bruxism was equated with dental wear, although the validity of tooth wear as an indicator of current bruxism activity has been questioned.[29]

The existence of distinct subgroups of bruxers has been reported previously.[25] However, the authors believe that the present study is the first to show a striking contrast in the level of pain experienced by the two subgroups of bruxers (one without pain, the other with high pain). The cause of this dichotomy in pain levels is unclear, although it is possible that the difference can be found in the level or frequency of jaw muscle activity. Muscles can adapt rapidly to exercise, and in so doing, they become more resistant to the damaging effects of repeated bouts of the same exercise.[30–32] The pain-free subjects may be comparable to well-trained athletes whose muscular endurance has been improved by practice. This hypothesis is supported by our preliminary results showing that the mean number of bruxing episodes (both tonic or phasic) per sleep hour appear to be higher in the pain-free bruxers (unpublished data). On the other hand, pain experienced by the bruxers with pain may be analogous to postexercise muscle soreness induced by an excessive loading.[33,34] This suggestion is supported by the observation that the pain of the large majority was usually worst in the morning, then faded gradually during the day. In postexercise muscle soreness, damage can occur to the muscle fibers themselves and/or to the connective tissue, causing edema, inflammation, and swelling.[32,35–38] Because postexercise muscle soreness often follows work performed by untrained muscles,[39–41] it can be expected to be common in patients with occasional bruxism. Indeed, Rugh and Solberg[42] found that fluctuating pain reported by their patients coincided with the periods of high levels of electromyographic activity in the masseter muscles. However, there is always a possibility that bruxism and myofascial pain coexist, and it was recently shown that exercise increases pain in the majority of myofascial pain patients.[43] This could explain why the pain level in bruxers appeared to be significantly higher than that of myofascial pain patients who do not brux.

Our data also show that the negative impact on function is higher in patients who had pain than in bruxers who were pain free, particularly with respect to mastication. Pain on chewing is a common complaint of patients with TMD (37% to 68%),[2,3,19,22] particularly for those with myofascial pain (up to 81%).[3,43] The same proportion was found among bruxers with pain (83.3%). This is in accordance with the reports that pain can lead to impairment of muscular performance or limitation of movements in patients with myofascial pain of the masticatory muscles and elsewhere.[44–48]

The majority of patients, particularly those in pain, reported having disturbed sleep. This is not surprising because many chronic-pain patients complain that they sleep poorly.[49] Fricton et al[2] reported that 42% of their myofascial pain patients complained of poor sleep, and Harness et al[6] found that sleep disturbances were more prevalent in myofascial pain subjects (67%) than in patients with "internal derangement" or atypical facial pain. It is also one of the most characteristic symptoms associated with fibromyalgia.[50–52] Among the bruxers who were pain free, 30% reported disturbed sleep, perhaps because orofacial motor episodes are often associated with body movements[53–54] and periods of arousal.[55–59]

## Conclusion

The present data indicate that there are at least two distinct subgroups of bruxers, one with no pain and another characterized by moderate to severe pain on awakening. Furthermore, the data suggest that bruxism and myofascial pain of the masticatory muscles may be distinct entities and that they are likely to have different etiologies. Because the number of bruxers included in the study was small and the two groups were studied at different times, further studies with larger populations need be done to confirm the observations.

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## Resumen

Comparación del dolor y la calidad de vida entre pacientes que padecen de bruxismo o de dolor miofacial de los músculos masticatorios

Aunque se ha indicado que el bruxismo es una causa o un factor de riesgo en el dolor miofacial de los músculos masticatorios; la prevalencia del dolor en los bruxómanos y sus características todavía no han sido evaluadas o comparadas a aquellas de los pacientes que presentan dolor miofacial en general. En este artículo se registraron, auto-reportes sobre el dolor y la calidad de la vida, en análogos visuales de 100 mm y escalas categóricas de cinco puntos en dos poblaciones experimentales. La primera consistió de 19 bruxómanos nocturnos que habían participado en un estudio polisomnigráfico; y la segunda consistió de 61 pacientes que habían participado en un estudio clínico controlado, sobre la eficacia de férulas orales y que padecían de dolor miofacial en los músculos masticatorios sin haber evidencia de bruxismo. La información indicó que el dolor fue mas intenso en los bruxómanos que se quejaron de dolor, en comparación a los pacientes con dolor miofacial, aún cuando el dolor no fue la queja principal de los bruxómanos. Ambas condiciones desmejoraron la calidad de vida del paciente, aunque los pacientes que padecían de dolor (ya sea por bruxismo o por dolor miofacial) parecían estar mas afectados que aquellos que bruxaban pero que no tenían dolor. El hecho de que el dolor como consecuencia del bruxismo fue peor en la mañana indica que es posiblemente una forma de sensibilidad muscular después de hacer este ejercicio. Es posible que el dolor miofacial, el cual empeoró hacia el final del día, tenga una etiología diferente.



## Zusammenfassung

Vergleich von Schmerz und Lebensqualität bei Bruxern und bei Patienten mit muskulärem Schmerz der Kaumuskulatur

Obwohl vorgeschlagen worden ist, dass Bruxismus eine Ursache oder ein Risikofaktor für myogene Schmerzen im Kausystem darstellt, sind Prävalenz und Qualität von Schmerzen bei Bruxern noch nicht beurteilt oder verglichen worden mit jenen von Patienten mit myogenen Schmerzen im Allgemeinen. Es werden Selbstberichte über Schmerz und Lebensqualität auf einer 100 mm VAS und auf einer 5-Punkte Kategorienskala bei zwei untersuchten Populationen festgehalten: *(1)* 19 nächtliche Bruxer, welche an einer polysomnographischen Studie teilnahmen und *(2)* 61 Patienten mit Kaumuskelschmerzen mit keinerlei Hinweisen auf Bruxismus, welche in einem kontrollierten klinischen Versuch über die Wirkung oraler Schienen teilnahmen. Die Resultate zeigten, dass der Schmerz bei Bruxern mit Schmerzen intensiver war als bei den Patienten mit myogenen Schmerzen, obwohl der Schmerz nicht die Hauptbeschwerde der Bruxer darstellte. Beide Zustände reduzierten die Lebensqualität der Patienten, auch wenn Schmerzpatienten (entweder bei Bruxismus oder bei myogenem Schmerz) wesentlich mehr als schmerzfreie Bruxer davon betroffen schienen. Die Tatsache, dass der Schmerz durch Bruxismus am Morgen am stärksten war, zeigt, dass es sich möglicherweise um eine Form von Muskelschmerz nach Belastung handelte. Muskulärer Schmerz, welcher sich am stärksten später im Tag manifestiert, dürfte eine andere Ätiologie haben.

# Differentiation Between Musculoligamentous, Dentoalveolar, and Neurologically Based Craniofacial Pain With a Diagnostic Questionnaire

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*A self-administered questionnaire consisting of 21 questions, diagrams for chief pain location, and a digital pain scale was used prospectively to sort 92 patients with orofacial pain into three categories:* (1) *musculoligamentous (ie, temporomandibular disorders);* (2) *neurologically based (ie, migraine, trigeminal neuralgia, tension-type headache, cluster headache, and atypical facial pain); and* (3) *dentoalveolar pain. Sensitivity, specificity, as well as negative and positive predictive values suggest that this questionnaire may be used reliably to identify patients with orofacial pain that fits the above-described pain categories without prior knowledge of the clinical diagnosis. Digital pain scale findings indicated that on presentation, pain level could not be correlated with any particular pain category, but when using this scale to describe past pain experience, patients with neurologically based pain selected the highest digital pain scale values up to six times more frequently than patients with musculoligamentous or dentoalveolar pain. Patients with musculoligamentous or dentoalveolar pain selected the lowest digital pain scale values up to 15 times more frequently than those with neurologically based pain. Although this questionnaire may be used for initial categorization of pain, there is still no substitute for a thorough history and clinical examination.*
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Since the true costs of chronic facial pain to society have been estimated to be several billion dollars,[1] it is essential that an accurate diagnosis be made as early as possible. In this regard, it is common for patients[2] to seek multiple opinions prior to obtaining an appropriate diagnosis. Moreover, patients must often wait lengthy periods of time for an assessment. Patients sometimes wait many months to be assessed in a temporomandibular joint (TMJ) clinic only to be told that they do not have a TMJ (or temporomandibular disorder [TMD]) problem, and instead they must be seen by the appropriate medical practitioner (eg, neurologist). Furthermore, patients seeking care from their primary care-giver may be treated inappropriately for pain conditions with overlapping symptoms. Thus, it is clear that a valid, yet easily administered and analyzed, diagnostic tool is required to circumvent some of the problems outlined above. With such an instrument, it might be possible to, in effect, rank patients immediately upon referral so that they can be assessed and treated more efficiently by the most suitable clinician.

The difficulty and frustration related to the diagnosis and subsequent treatment of patients with chronic orofacial pain may be

attributable in part to the multidimensional nature of pain. Several different facial pain conditions exist, often with overlapping signs and symptoms, and this tends to add another level of complexity to the diagnosis and management of chronic orofacial pain.[3] To characterize the syndromes of patients with pain more reliably and efficiently, various types of questionnaires have been developed.[4-6] For example, the McGill Pain Questionnaire is used widely to assess pain, but it is used rarely as a diagnostic instrument.[4] Other questionnaires, indexes, and assessment tools have been developed and utilized to differentiate among various facial pain conditions, such as TMJ pain, trigeminal neuralgia (TN), atypical facial pain (AFP), cluster headache (CH), muscle contraction headache (MCH), migraine headache (M), and others.[7-13] However, many of these instruments are quite cumbersome and hence difficult for the patient to complete and for the examiner to analyze.

To date, there are few easily administered multidimensional diagnostic tools for the assessment of chronic orofacial pain. The purpose of this study was to develop a simple, self-administered questionnaire to differentiate between three broad groups of pain in patients: *(1)* musculoligamentous pain, such as in TMD; *(2)* neurologically based pain, such as in TN, M, AFP, CH, and MCH; and *(3)* dentoalveolar pain, such as in tooth or periodontal pain. This tool was developed with the aid of a previous questionnaire[14] used in a pilot study of 117 patients. The new questionnaire consisted of 21 questions, a digital pain scale (DPS),[15] and diagrams for pain location. With this questionnaire, it may be possible to initially categorize a patient's facial pain condition, which would permit patient referral to the appropriate care-giver in a more timely manner. Furthermore, this might prevent inappropriate treatment for pain conditions with overlapping symptoms.

## Materials and Methods

### Study Design

The questionnaire, consisting of 21 questions, a DPS, and diagrams for pain location, was administered to 92 patients (group 1) presenting consecutively to the Craniofacial Pain Research Unit at the Mount Sinai Hospital (Toronto, Canada) with complaints of craniofacial pain. Each patient was asked to complete the self-administered questionnaire prior to undergoing his or her first clinical assessment. The history and clinical examination were conducted by one of four investigators for establishment of a clinical diagnosis. In cases involving neurologically based conditions, all diagnoses were made by one of two neurologists (AG, MS) with considerable expertise in the area of facial pain. Commonly accepted criteria, described by the International Headache Society,[16] were used for diagnosis of TN, MCH, M, and CH. The diagnosis of AFP was also confirmed by a neurologist according to criteria suggested by others.[17] Diagnoses of musculoligamentous pain or dentoalveolar pain were made by one of two dentists (DM, HCT) according to well-defined clinical criteria as described elsewhere.[18,19] The questionnaires were analyzed by another investigator (LH) who was blinded to the clinically determined diagnoses to derive an unbiased instrument-based differential diagnosis. Similarly, the clinical diagnoses were established without knowledge of the instrument-based assessment. The instrument-based diagnoses were then compared to the clinical diagnoses (gold standard) and the findings subjected to statistical evaluation.

### Development of the Questionnaire

A previous questionnaire[14] had been administered to a group of 117 patients attending the pain clinic in a pilot investigation. This questionnaire consisted of 67 questions and 9 diagrams for pain location. The questions were divided into a number of categories including, but not limited to: pain intensity (0 = no pain; 1 = slight pain; 2 = quite a bit of pain; 3 = extreme pain) and pain frequency (0 = never; 1 = rarely; 2 = sometimes; 3 = most of the time or always). The answers to questions were analyzed retrospectively to identify responses that could be correlated with a particular clinical diagnosis, such as TMJ pain, myofascial (MYO) pain, combined TMJ/MYO pain, AFP, TN, M, CH, tension-type or MCH, and dentoalveolar pain, in the following manner: The answers were concatenated such that responses of 0 or 1 were considered negative, and responses of 2 or 3 were considered positive. Questions that resulted in a positive response for a particular diagnosis at least 60% of the time were designated "inclusionary" for that diagnosis. Questions that resulted in positive responses less than or equal to 10% of the time were designated as "exclusionary." On this basis it was possible to decrease the number of questions in the questionnaire to 21 (Table 1). As an internal control, two questions were repeated within the questionnaire.

**Digital Pain Scale.** A DPS was used for patients to express their perception of the severity of their own pain, and it consisted of two horizontal

**Table 1** Diagnostic Questionnaire

| No. | Question |
|---|---|
| 1 | My principal pain is constant without any pain free intervals. |
| 2 | My principal pain is located externally, on my skin. |
| 3 | My principal pain starts when I lightly touch that area on my face. |
| 4 | My principal pain starts or gets worse when I drink/eat hot or cold things. |
| 5 | My principal pain occurs intermittently in a non-predictable pattern, with pain-free intervals. |
| 6 | When I have my principal headache, any bright light or noise annoys me more. |
| 7 | My jaw makes a grating, grinding, popping, or clicking noise when I chew, eat or talk. |
| 8 | My principal pain is only on ONE side of my head or face and it is always on the SAME side. |
| 9 | My principal pain is at its maximum at the beginning. |
| 10 | My principal pain makes me feel sick to my stomach (nauseated). |
| 11 | My pain gets worse the more I move my jaw when eating, chewing, or talking. |
| 12 | My principal pain is sometimes on one side and sometimes on the other, at different times. |
| 13 | I hear clicking or popping from my jaw before the pain starts. |
| 14 | My principal pain comes in clusters, everyday for several days or weeks, with long pain-free intervals (weeks, months). |
| 15 | My principal pain is located externally, on my skin. |
| 16 | My principal pain is NOT constant, there are pain-free intervals between bouts of pain. |
| 17 | My principal pain is getting worse over time. |
| 18 | I feel pain when I press hard on the back of my neck. |
| 19 | My jaw pops or clicks when I open my mouth wide. |
| 20 | My principal pain is on BOTH sides of my head or face at the SAME time. |
| 21 | My jaw pain gets worse the more I move my jaw (eat hard food, talk, or chew). |

Rating scale: 0 = never, none of the time; 1 = rarely; 2 = sometimes; 3 = always, most of the time. 0 or 1 = negative response; 2 or 3 = positive response.

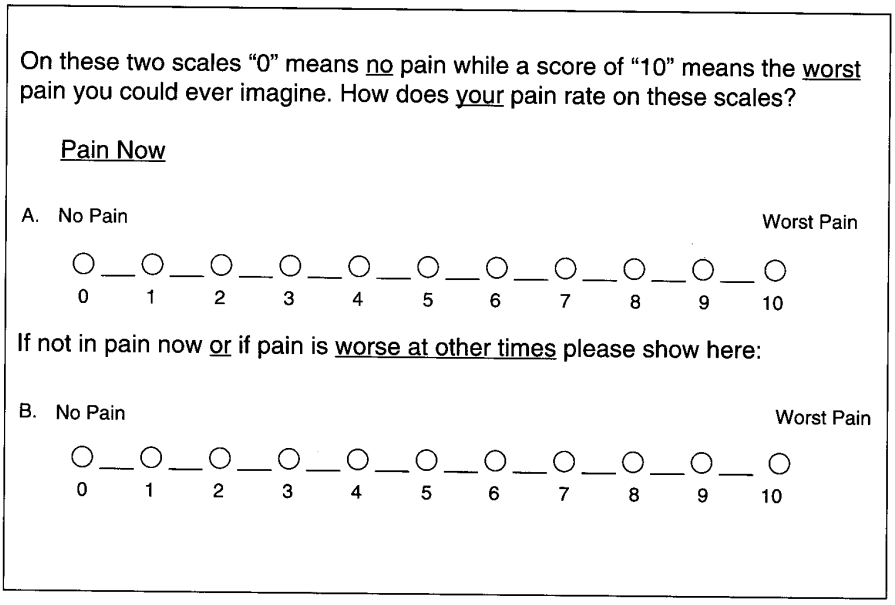


**Fig 1** These scales were used for patients to express their perception of the severity of their pain. The scale ranged from 0 to 10, with 0 representing "no pain" and 10 representing the "worst pain you could ever imagine." Patients were asked to complete both DPS-A, which represented pain on presentation, and DPS-B, which represented pain at other times if more severe.

lines with graded markings 1 cm apart (Fig 1). The scale ranged from 0 to 10, with 0 representing no pain and 10 represented the "worst pain you could ever imagine." Patients were asked to complete both lines such that the top line (DPS-A) represented pain on presentation and the second line (DPS-B) represented pain at other times if more severe (ie, past pain experience). Findings from an earlier retrospective study[15] using this scale indicated that patients with AFP selected a value of "9-10" at least four times more frequently than those individuals with, for example, musculoligamentous pain ($P < .05$), but only on the DPS-B. To confirm and expand these findings, the same DPS was

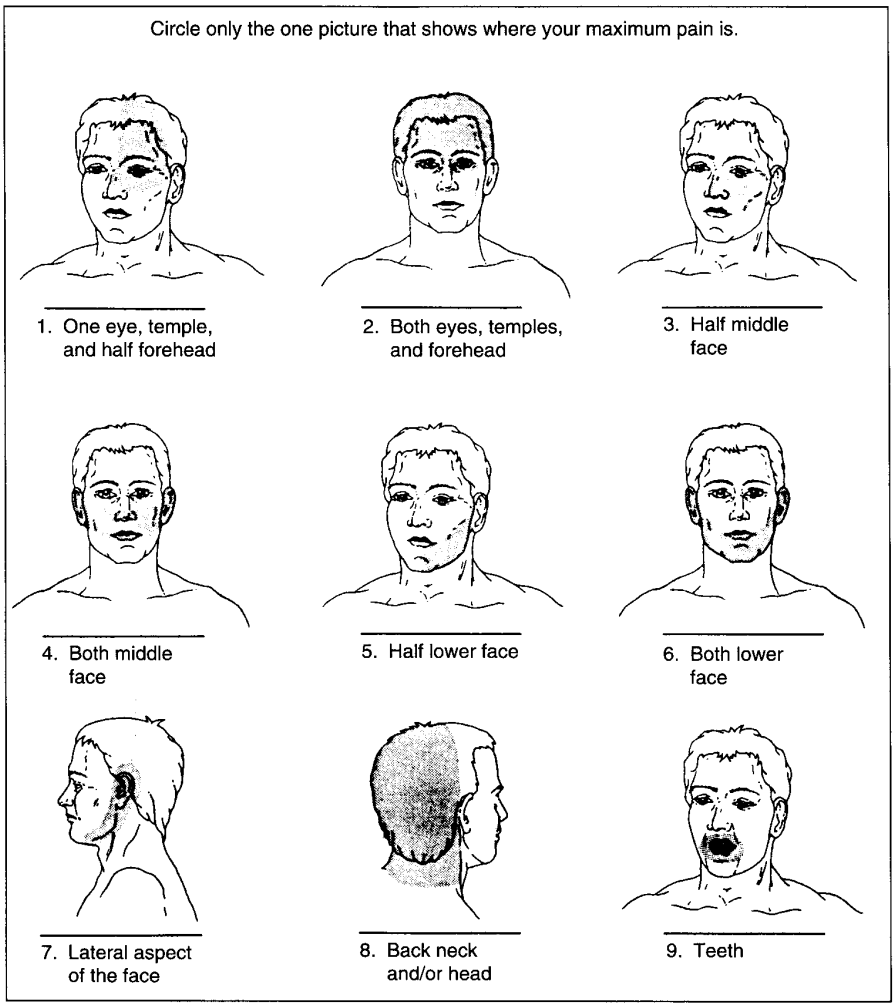


**Fig 2** Patients were instructed to select one of the diagrams, which indicated the location of their principal pain.

administered to an additional group of 130 patients (group 2) separate from those participating in the diagnostic questionnaire study. The group 2 values obtained for both DPS-A and DPS-B were correlated to the clinically determined facial pain conditions described above. As for the complete questionnaire, clinical diagnoses were established without knowledge of the DPS scores and all diagnoses were established according to criteria described elsewhere.[16–19] To exploit the putative discriminative capacity of the DPS already suggested in the earlier investigation,[15] it was appended to the diagnostic questionnaire to aid the investigator in differentiating between AFP and musculoligamentous conditions.

**Pain Diagrams.** The McGill Pain Questionnaire utilizes pain diagrams or body maps to indicate the spatial distribution of pain.[4] It has been suggested that pain distribution may be used as an indicator for certain pain conditions more than other parameters.[18,19] The original 67-question instrument used in the pilot study incorporated this concept and contained 9 diagrams (Fig 2). Each patient was instructed to select one diagram that indicated the location of their principal pain. From these results it was possible to construct polar graphs for pain distribution (Fig 3) that were representative of the various diagnoses.

## Analysis

**Assessment of Diagnostic Accuracy.** The instrument-based differential diagnoses were categorized into one of three groups:

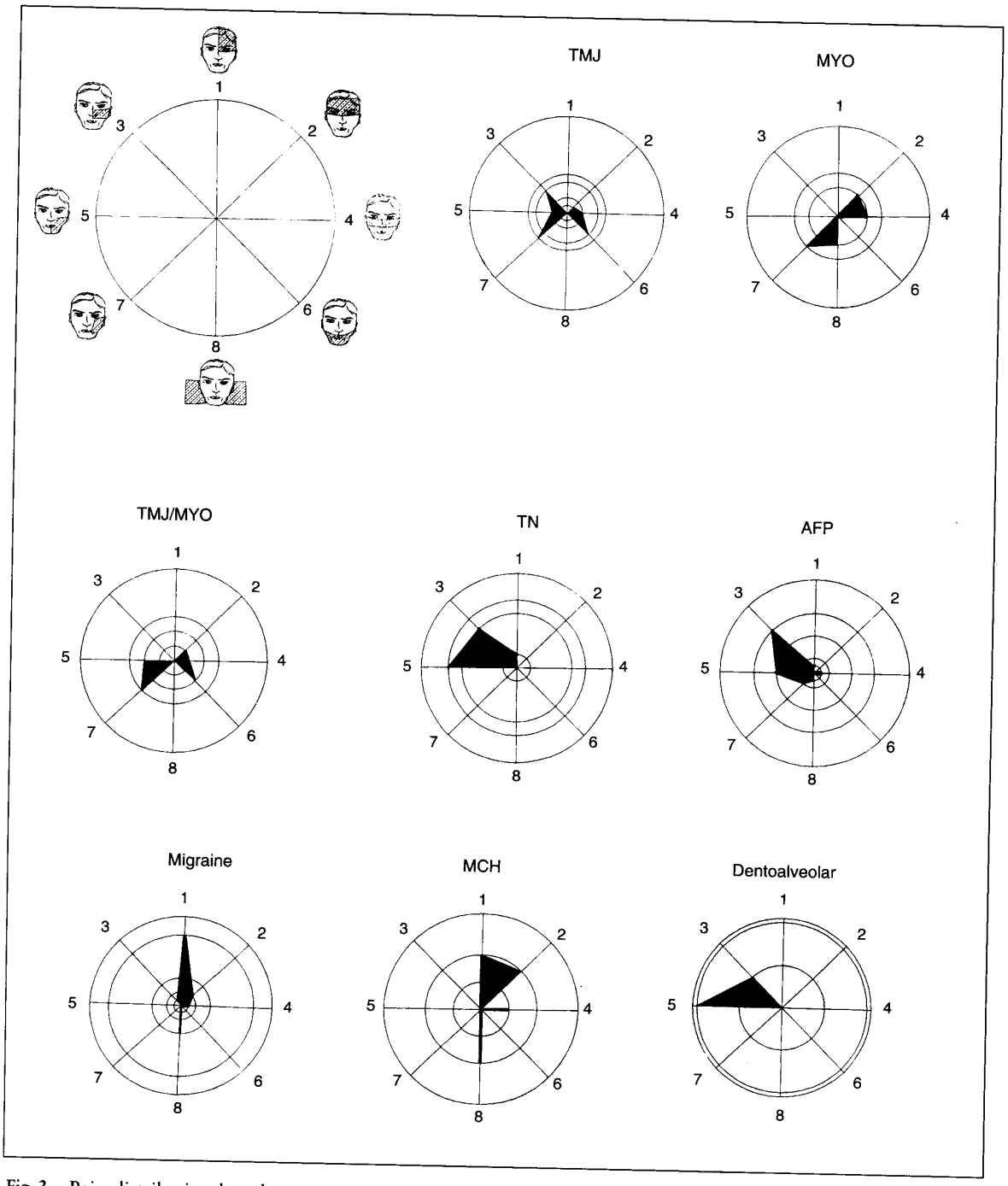


Fig 3 Pain distribution based on patient selection of diagrams in a pilot study was used to construct these polar graphs. Each graph depicts a unique pain distribution pattern for each diagnosis. The center point represents 0%, and the outer perimeter approaches 100%. In some instances, the outer perimeter is not shown. Each bin depicts a pain location diagram, and thus, the percentage of patients with a specific diagnosis was represented on the axis (perpendicular to outer perimeter) in each bin. The values on each axis were connected to one another. The resulting circumscribed area was filled (black) to generate a unique pattern or "fingerprint" for each diagnosis.

1. Musculoligamentous pain encompassing the TMDs consisting of TMJ pain, MYO pain, or a combination of TMJ and MYO pain.
2. "Neurologically based" conditions including AFP, TN, M, CH, and MCH.
3. Dentoalveolar pain (eg, tooth or periodontal pain).

The clinical diagnosis (gold standard) was made by one of four investigators using accepted clinical criteria, as indicated above.[16–19] Comparison of the instrument-based diagnoses to the gold standard (clinical diagnoses) permitted calculation of various test parameters including positive predictive value (PPV), negative predicative value (NPV), sensitivity, and specificity for the three groups. Analysis of variance (ANOVA) and Student's *t*, chi-square, Fisher's Exact, and McNemar's tests were used to calculate differences in DPS scores for the various subgroups. Kappa values were also determined and listed.

**Determination of Instrument-Based Diagnosis.** An instrument-based diagnosis was generated by analyzing the results of the 21-item questionnaire without prior knowledge of the clinical diagnosis. A determination of either neurologic, musculoligamentous, or dentoalveolar pain was made if a majority (> 50%) of inclusionary questions for the particular condition was answered in the affirmative. Exclusionary questions were weighted similarly. If the examiner was unable to narrow the number of differential diagnoses to two or less on the basis of the inclusionary or exclusionary questions alone, the DPS was used. In this regard, a DPS-B value of 9 to 10 would be used to differentiate AFP from the TMDs because these conditions often overlapped. If the number of choices still remained above two, the polar graphs for pain were then utilized to determine the most appropriate diagnostic category for the patient. An example of this process is provided in Table 2.

**Table 2** Interpretation of the Diagnostic Questionnaire From One Patient

| Diagnosis | No. affirmative answers/ total inclusionary questions |
|---|---|
| TMJ pain | 2/8 |
| Myofascial pain | 2/8 |
| Combination TMJ/myofascial pain | 2/6 |
| Atypical facial pain | 3/3 |
| Trigeminal neuralgia | 1/3* |
| Muscle contraction headache | 1/3* |
| Cluster headache | 1/6* |
| Migraine headache | 2/4 |
| Dentoalveolar pain | 1/3 |

*Eliminated at the outset based on answers to the exclusionary questions. Based on the above findings an initial diagnosis of atypical facial pain (AFP) was inferred. The DPS-B for this patient was 9, which was also considered to be indicative of AFP. This diagnosis was strengthened further by the fact that the patient had selected a diagram depicting pain in a unilateral, upper half distribution (as shown in Fig 3, the polar graphs indicate such a pain distribution in the AFP patient population). Thus, based on the questionnaire, a diagnosis of AFP was selected, and the patient was entered into the neurologic pain category.

**Table 3** Instrument-Based Diagnosis Versus Gold Standard Diagnosis for the Three Diagnostic Groups

| | Musculoligamentous pain | Neurologically based pain | Dentoalveolar pain |
|---|---|---|---|
| True positive responses | 37 | 15 | 3 |
| False positive responses | 5 | 12 | 2 |
| True negative responses | 22 | 43 | 64 |
| False negative responses | 10 | 4 | 5 |
| Sensitivity | 78.70% | 78.90% | 37.50% |
| Specificity | 81.50% | 78.20% | 97.00% |
| PPV | 88.70% | 55.60% | 60.00% |
| NPV | 68.80% | 91.50% | 92.80% |
| Kappa | 0.58% | 0.50% | 0.41% |

## Results

The findings suggest that it is possible to establish, by way of a self-administered questionnaire, a reliable determination of the nature of a given patient's pain condition. In this regard the instrument-based assessments were compared to the gold standard (clinical assessments) as shown in Table 3 to ascertain sensitivity, specificity, PPV, and NPV for the three broad diagnostic categories: musculoligamentous, neurologic, and dentoalveolar. Kappa values, which refer to the proportion of agreement beyond chance that was actually achieved between observers (in this case, clinical versus instrument-based), were also determined (Table 3). The findings indicate further that sensitivity of this diagnostic questionnaire was 78.70%, 78.90%, and 37.50% for the musculoligamentous, neurologic, and dentoalveolar groups respectively, and specificity was 81.50%, 78.20% and 97.00% for the same three groups. The PPV and NPV for the musculoligamentous group was 88.10% and 68.80%; for the neurologic group, 55.60% and 91.50%; and for the dentoalveolar group, 60.00% and 92.80% respectively.